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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/736,199 | 12/15/2003 | Peter Douglas | ETH5099 | 4355 |
| 23389 | 7590 | 04/10/2007 | EXAMINER | |
| SCULLY SCOTT MURPHY & PRESSER, PC | | | EREZO, DARWIN P | |
| 400 GARDEN CITY PLAZA | | | ART UNIT | PAPER NUMBER |
| SUITE 300 | | | 3731 | |
| GARDEN CITY, NY 11530 | | | | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/10/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/736,199 | DOUGLAS ET AL. |
| | Examiner | Art Unit |
| | Darwin P. Erez | 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
 - 4a) Of the above claim(s) 13 and 15-17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12, 14 and 18-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 December 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/03, 5/9/05</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species II in the reply filed on 01/24/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 13 and 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/24/2007.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on 12/15/03 and 5/9/05 have been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the lines, numbers and letters are not uniformly thick and well defined, clean (poor line quality). See 37 CFR 1.84(l). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-9, 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,749,828 to Solomon et al.

(claims 1 and 14) Solomon discloses a variable stiffness malleable shaft comprising:

plurality of prismatic shaft adjacent one each having:

a first longitudinal axis (see Fig.6);

a plurality of axial through holes (shown better in Fig. 7);

a recess **16** formed in a distal end of the shaft element, the recess defined along a second axis transverse to the first longitudinal axis;

a protrusion **14** formed in a proximal end of the shaft element, the protrusion defined along a third axis transverse to the longitudinal axis, wherein

the second and third axes are oriented relative to one another such that the respective axial through holes of adjacent like shaft elements are aligned with one another;

and at least one tension element **13a,13b** secured to a distal end of the shaft.

Solomon discloses all the limitations of the claim, except for the recess being formed in the proximal portion and the protrusion being formed in the distal section. Instead, Solomon discloses the opposite, as cited above. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have recess formed in the proximal section and the protrusion formed in the distal section, since it has been held that a mere reversal of essential working parts of a device involves only routine skill in the art. *In re Gazda*, 219 F.2d, 449, 104 USPQ 400 (CCPA 1955).

(claims 2-4) Solomon discloses a bendable shaft for use with remote medical devices, such as endoscopes (col. 1, line 11), that passes within the lumen of the shaft.

(claim 5) There is a central axial through hole, as seen in Fig. 7.

(claims 6 and 7) The recess and the protrusion comprises friction enhancing means via the finger-shape joint of the protrusion **17** and the finger-shape socket of the recess **19** and the material used to form the shaft.

(claim 8) Solomon discloses a base in the proximal end of the shaft, as seen in Fig. 6.

(claim 9) Solomon discloses the recess and the protrusion being offset by 90 degrees, as seen in Fig. 6.

(claims 11 and 12) As stated in claim 9, Solomon discloses the recess and the protrusion being offset by 90 degrees. Fig. 7 also shows three axial through holes being offset by 90 degrees and 135 degrees. Solomon is silent with regards to the recess and the protrusion being offset by 120 degrees or the three axial through holes being distributed by 120 degrees. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the recess and the protrusion to be offset by 120 degrees, or to the three axial through holes being distributed by 120 degrees, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Furthermore, it would have been an obvious matter of design choice to have the recess and the protrusion be offset by 120 degrees, or for the three axial through holes to be distributed by 120 degrees, since the arrangement of the recess and the protrusion and the distribution of the axial through holes is merely dependent upon the intended flexibility of the shaft, which is dependent upon the intended surgical procedure.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al. and in view of US 6,364,828 to Yeung et al.

Solomon discloses the device having a plurality of axial through holes comprising three axial through holes. Solomon fails to disclose the use of four axial through holes spaced at 90 degrees from one another. However, Yeung discloses a similar bendable

shaft as Solomon, wherein the shaft includes four axial through holes spaced at 90 degrees from one another, as shown in Fig. 1-3. The inclusion of a fourth axial through hole provides additional control for the bendable shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Solomon to include a fourth axial through hole and arrange the through holes at 90 degrees from each other because it would provide the user with additional control for manipulating the bendable/steerable shaft.

9. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,381,782 to DeLaRama et al.

(claim18) DeLaRama discloses an actuator for a variable stiffness shaft comprising: a first pair of tension elements **76**; a fulcrum **80**; an actuator (the top portion of handle **24a**); and a connector linking the fulcrum to the actuator (the portion of the handle **24a** that connects to the fulcrum). DeLaRama fails to disclose the proximal ends of the tension element passing over a proximal side of the fulcrum. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the fulcrum to have the tension elements passing over the proximal side of the fulcrum because Applicant has not disclosed that said arrangement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the fulcrum shown in Fig. 10 of DeLaRama or the claimed arrangement because both arrangements perform the same function of actuating the tension elements.

Therefore, it would have been obvious matter of design choice to modify the fulcrum of DeLaRama to obtain the invention as specified in claim 18.

(claim 19) The fulcrum is spherical, as shown in Fig. 10.

(claims 20-22) The fulcrum has a channel that leads to its proximal end section, as seen in Fig. 10. Therefore, the modification as described in claim 18 to have the tension elements pass over to the proximal side of the fulcrum will also modify the channels to be located in the proximal side of the fulcrum to prevent the tensioning elements from moving freely around the fulcrum. The channel will also be aligned with a great circle of the spherical fulcrum.

10. Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLaRama et al. in view of Yeung et al.

DeLaRama discloses an actuator for use with three tensioning elements. However, it is well known in the art to have four tensioning elements, as shown by Yeung in Fig. 1. Therefore, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to modify the fulcrum to support four tensioning element since it is well known in the art for malleable shafts to have between two to four tensioning elements. Furthermore, it would have been obvious to duplicate one of the channels to provide a fourth channel since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d, 669, 124 USPQ 378 (CCPA 1960).

The modified device of DeLaRama is still silent with regards to a second channel being deeper in the fulcrum or the first and second channel being formed as cross.

However, it would have been an obvious matter of design choice for the fulcrum to have said arrangement because the tensioning elements of Yeung are disposed at 90 degrees to each other and would therefore cross each other at the proximal end of the fulcrum. It would also be an obvious matter of design choice to have a channel to be deeper than the other channel because it would prevent the tensioning elements from lying on top of each other. Furthermore, the applicant has not provided any criticality for the claimed limitations because the grooves or the overlap are taught to be optional (paragraph [0039]).

Conclusion

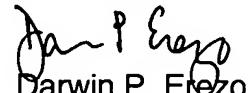
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Darwin P. Ezezo
Examiner
Art Unit 3731

de